IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

BOND PHARMACY, INC., d/b/a AIS HEALTHCARE,

Plaintiff

v. **CIVIL ACTION NO.: 3:23-CV-03158-CWR-LGI**

MERRICK GARLAND, in his official capacity as the Attorney General of the United States, 950 Pennsylvania Avenue, NW, Washington, DC 20530-0001;

U.S. DEPARTMENT OF JUSTICE, 950 Pennsylvania Avenue, NW, Washington, DC 20530-0001;

ANNE MILGRAM, in her official capacity as the Administrator of the Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; and

DRUG ENFORCEMENT ADMINISTRATION, 8701 Morrissette Drive, Springfield, VA 22152;

Defendants.

PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR EMERGENCY TEMPORARY RESTRAINING ORDER

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INTRODUCTION

This is a dire case in which the Court is called on to act immediately to stave off grave and irreparable harms to the plaintiff, its patients, and the public. Plaintiff Bond Pharmacy, Inc., d/b/a AIS Healthcare ("AIS"), a leading provider of highly-specialized intrathecal home infusion therapy ("HIT") services, seeks a Temporary Restraining Order ("TRO") prohibiting the Honorable Merrick Garland, in his official capacity as the Attorney General of the United States, the U.S. Department of Justice, the Honorable Anne Milgram, in her official capacity as Administrator of the Drug Enforcement Administration ("DEA Administrator"), and the Drug Enforcement Administration ("DEA"), and anyone acting on their behalf (collectively, "the Defendants"), from enforcing a heavy-handed and blatantly unlawful cease and desist letter directive executed on December 12, 2023, and received by AIS on December 14, 2023.

With their directive, Defendants demand that AIS immediately cease and desist from shipping its custom medications – used to treat over 34,000 of the nation's sickest patients – directly to their treating physicians to be refilled in their intrathecal pumps. AIS thus faces an impossible Hobson's choice: Deny tens of thousands of patients access to their vital, pain-reliving medications and put them at grave risk of additional medical problems and jeopardize AIS's very existence, or face criminal and civil liability for continuing to dispense its medications to protect the health, safety, and well-being of its patients.

Faced with such obvious and grave irreparable harms – as well as the fact that Defendants' directive plainly violates federal laws and AIS fundamental constitutional rights – the Court should issue immediate preliminary relief to prevent any further harm to AIS, its patients, and the public at large.

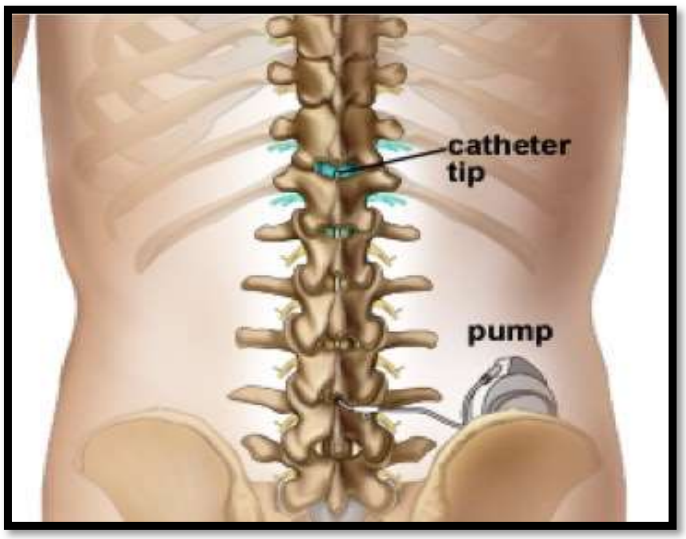
BACKGROUND

AIS Provides Specialized HIT Services To Critically Ill And Vulnerable Patients

AIS is a licensed compounding pharmacy and healthcare provider, registered with the DEA, that offers specialty HIT and related services. Verified Complaint ("Cmplt.") ¶ 21. HIT is the creation, dispensing, and infusing of medication by non-oral means. *Id.* ¶ 22. Under this therapy, patients receive a continuous, daily treatment at home – as opposed to an in-patient, hospital setting – and can resume normal lifestyles and work activities while recovering from illness. *Id.* ¶ 23.

If HIT were not available, these patients would either have to take mind-addling oral opioids (and be exposed to their potentially devastating side-effects), or live out their days in an in-patient treatment facility. *Id.* ¶ 24. HIT is typically prescribed for patients who have serious and abiding illnesses such as chronic pain from cancer, spinal cord injuries, multiple sclerosis, or other debilitating conditions. *Id.* ¶ 25.

AIS operates in a specialized area of HIT. *Id.* ¶ 26. It develops and dispenses patient-specific compounded pain medications at the direction of a patient's treating physician that are continuously infused via implanted intrathecal pumps. *Id.* These pumps, which are prescribed by a patient's treating physician, are surgically implanted under the patient's skin and filled with medication that the pump administers through a catheter to the spinal column wherever the patient is located, as the following illustration shows:



[1]

Intrathecal pumps can administer a patient's medication daily for up to 180 days before needing to be refilled. *Id.* ¶ 28. The medications used for intrathecal pumps have to be specially prepared for each patient to remain stable, sterile, and effective for up to 180 days between refills. *Id.* ¶ 29. These medications are not readily available from retail commercial pharmacies; they must be developed for each patient in sterile environments and using specialized and highly-technical procedures. *Id.* ¶ 30.

Thus, AIS's patients cannot readily obtain the same medications from retail pharmacies or even competitors. *Id.* ¶ 31. Indeed, AIS is one of the largest intrathecal HIT providers in the country and, unlike other providers, cares for patients in all 50 states who count on continued access to its therapy. *Id.* But AIS does more than develop custom medications. *Id.* ¶ 32. AIS provides all patients with access to a host of ongoing care and services, such as clinical services, coordination of patient care, nursing services, and billing support services. *Id.*

Critically, a patient's intrathecal pump must remain filled with medication at all times. *Id.* ¶ 33. Without the medication, the pump cannot properly function. *Id.* They are designed to have

[1] Mayfield Clinic, *Pain Pump*, at 1, https://d3djccaurgtij4.cloudfront.net/pe-pain-pump.pdf (last visited Dec. 15, 2023).

medication flowing through them at all times. *Id.* And without consistent access to an intrathecal HIT provider's specially-compounded medications, chronically ill and vulnerable patients will remain in constant pain and misery – all of which intrathecal HIT is specifically designed to treat. *Id.* ¶ 34. Patients with dry pumps may also face serious harm – even death. *Id.* ¶ 35. When a pump runs dry, a patient can go into severe withdrawal and suffer other significant and harmful side effects. *Id.* ¶ 36. For example, a patient suffering from multiple sclerosis can lose control of spasticity that would otherwise be treated with AIS's therapy, leading to possible seizures and strokes. *Id.* ¶ 37. Moreover, without access to AIS's medications, these patients will have to revert back to in-patient care, losing access to the freedoms associated with having their treatment and therapy follow them wherever they may go. *Id.* ¶ 38.

The Controlled Substances Act

The Controlled Substances Act ("CSA") establishes controls and restrictions on the import, export, manufacture, and distribution of controlled substances. 21 U.S.C. § 801 *et seq.*; *id.* § 951 *et seq.*; 21 C.F.R. Part 1300 *et seq.* The DEA is tasked with enforcing the CSA in a balanced manner that prevents the diversion of controlled substances from legitimate channels while ensuring their availability for legitimate medical purposes. *See* 76 Fed. Reg. 39,318 (July 6, 2011). The CSA requires all persons who dispense controlled substances to obtain a registration from the DEA. *See* 21 U.S.C. § 822(a); 28 C.F.R. § 0.100.

For a specialty pharmacy, such as AIS, this registration authorizes the pharmacy to dispense certain controlled substances. Cmplt. ¶ 43. Under the CSA's regulations, "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner." 21 C.F.R. § 1306.06. The administration and dispensing of narcotic drugs is further governed by 21 C.F.R. § 1306.07.

From July 25, 2005, to October 29, 2020, 21 C.F.R. § 1306.07 did not specifically address whether a pharmacy was permitted to dispense controlled substances to a treating physician, instead of directly to a patient. Cmplt. ¶ 46. On October 30, 2020, 21 C.F.R. § 1306.07 was amended to include subsection (f), which is still present in the regulation today. *Id.* ¶ 47. In relevant part, 21 C.F.R. § 1306.07(f) states "a pharmacy may deliver a controlled substance to a practitioner . . . if":

> "(1) The controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance," and
>
> "(2) The controlled substance is to be administered for the purpose of maintenance or detoxification treatment"; and
>
> (i) "The practitioner . . . is a qualifying practitioner"; and
>
> (ii) "The controlled substance is to be administered by injection or implantation";
>
> (3) "The pharmacy and the practitioner are authorized to conduct such activities specified in this paragraph (f) under the law of the State in which such activities take place[.]"

Thus, as the regulation makes clear on its face, its purpose is to ensure patients receive oversight and care while controlled substances and related treatments are administered. *See id.*

Under the CSA, the DEA can revoke, restrict, or suspend a registration upon a finding that the registrant has, among other things, "committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). But prior to revoking or restricting a DEA registration, DEA must follow mandatory procedures designed to provide a registrant with notice and an opportunity to be heard. *See generally id.* § 824. The DEA must issue an order to show cause setting forth the basis for the agency's proposed action, providing notice of the opportunity for the registrant to submit a corrective action plan, and providing the registrant with the opportunity to request a hearing. *See id.* §§ 824(c)(1)–(2). At such a hearing, the agency has the burden of proving by a preponderance of evidence that registration is inconsistent with the public interest. *See* 21 C.F.R. § 1301.44(d).

Alternatively, a registration may be immediately suspended upon a finding that there "is an imminent danger to the public health or safety" evidenced by a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 824(d). Thus, the DEA must comply with established procedures and protocols before acting to revoke or restrict a DEA registration or related actions. *See* 21 U.S.C. §§ 824(c)(1)–(2) & (d); 21 C.F.R. § 1301.44(e); *id.* § 1301.36(e).

The DEA Confirms That AIS's Dispensing Of Compounded Medications To Treating Physicians Is Permissible Under The CSA

On October 9, 2015, counsel for AIS contacted the DEA to seek guidance and clarity on whether a pharmacy – such as AIS – may deliver controlled substances to a treating physician, instead of directly to a patient, for refills under certain circumstances under the CSA. Exhibit ("Ex.") A.[2] AIS proactively sought guidance from the DEA because the CSA did not address such a scenario. Cmplt. ¶ 56. AIS wanted to ensure it fully complied with all applicable laws and regulations while providing its therapy and services. *Id.* ¶ 57.

The DEA responded to AIS's request on July 12, 2016. Ex. A. In its response, the DEA confirmed that "[n]either the CSA nor DEA regulations specifically address" delivering controlled substances to a treating physician under certain circumstances. *Id.* Nevertheless, the DEA confirmed that AIS's proposed practice of dispensing its medications to treating physicians fully complied with the CSA. *Id.*

The DEA used the following scenario to evaluate AIS's inquiry:

- "A DEA-registered practitioner, acting in the usual course of his/her professional practice, issues a prescription for a controlled substance for a legitimate medical purpose, and the prescription complies in all other respects with the DEA regulations.

[2] Exhibits referenced in this memorandum are attached to AIS's Motion for Emergency Temporary Restraining Order. L.U. CIV. R. 7(b)(2).

- The practitioner determines, in the exercise of his/her sound medical discretion, that it is appropriate for the practitioner to administer the controlled substance directly to the patient at the practitioner's registered location.

- The prescription is for a single dose of the controlled substance for a particular patient – not a take-home supply for that patient and not for the practitioner's office stock.

- The practitioner indicates on the prescription that the controlled substance should be delivered by the pharmacy to the practitioner, at his/her registered location, for administration to the patient.

- The above activity is carried out in compliance with applicable State law and regulations." *Id.*

Evaluating the scenario under which AIS would deliver its compounded medications to a treating physician, the DEA confirmed that it "*would consider it permissible* under the CSA and DEA regulations for [AIS] to deliver the controlled substance to the practitioner, at his/her registered location," provided the following conditions are met:

- "The pharmacy treats its actions as dispensing for purposes of the CSA and DEA regulations and complies with all applicable requirements thereunder," *id.*; and

- "The practitioner treats his/her actions as administering for purposes of the CSA and DEA regulations and complies with all applicable requirements thereunder," *id.*

Based on that guidance, AIS complied with the DEA's determination by meeting its identified conditions and direction. Cmplt. ¶ 63. AIS shipped patient medications to their treating physicians for refills *for years* without issue. *Id.* ¶ 64. Indeed, despite further routine inspections from the DEA and other boards and agencies, they never once raised concerns with AIS's dispensing practices or compliance with the CSA or noted any lack of compliance with the conditions it previously identified. *Id.* ¶ 65.

The DEA Improperly, Without Any Basis, And Directly Contrary To Its Earlier Direction And Guidance, Demands AIS Cease And Desist Dispensing Of Its Medications

On November 2, 2023, the DEA Jackson District Office conducted an on-site inspection of AIS. *Id.* ¶ 66. The inspection itself was standard and routine. *Id.* ¶ 67. During the inspection, the

DEA explained that it did not uncover any issues or concerns related to AIS's operations and procedures. *Id.* Notably, it did not find that AIS was out of compliance at all with its earlier guidance or conditions for dispensing medications to physicians.

But on December 14, 2023, the DEA – out of the blue – served a letter on AIS (dated December 12, 2023). Ex. B. In the letter, the DEA claimed that during its latest inspection, it "learned" that AIS had been "providing patient specific pain medications" to treating physician offices – even though AIS had been dispensing its medications to physicians for refills for years, as the DEA knew and previously approved of. *Id.* The DEA then quoted 21 C.F.R. § 1306.07(f) without expressly stating whether or not AIS complied with the regulation. *Id.* After quoting the regulation in the one-page letter, and without any further notice, explanation, or opportunity for AIS to respond, the DEA demanded that "AIS must cease and desist any further shipments of its compounded medications directly to [treating physicians]" of AIS patients from its Ridgeland-based pharmacy. *Id.* The DEA did not mention, let alone explain its departure from, its earlier guidance to AIS.

The Ridgeland, Mississippi pharmacy is AIS's most active pharmacy and dispenses the largest volume of AIS's medications to patients across the United States. Cmplt. ¶ 75. AIS cannot remain a going concern and meet its patients' medical needs if the Ridgeland pharmacy is shut down, even temporarily. *Id.* ¶ 76.

The DEA did not issue an order to show cause setting forth the basis for demanding AIS cease and desist its pharmacy shipments or afford AIS the right to request a hearing, as required under the CSA. 21 U.S.C. §§ 824(c)(1)–(2); Ex. B. Nor did the DEA establish by a preponderance of the evidence that AIS had violated the CSA and regulations – which it must do under the CSA – and cannot practically do in light of its earlier direction. *See id.* Likewise, the DEA failed to

provide a statement identifying an "imminent danger to public health or safety." 21 U.S.C. § 824(d)(1); Ex. B.

Within an hour of receiving the DEA's correspondence, AIS's counsel contacted the agency by telephone to resolve the issue. Cmplt. ¶ 79. Counsel for AIS further alerted the agency that it intended to seek preliminary relief should it refuse to engage or withdraw its unlawful directive. Exs. C & D. But the DEA never responded to AIS's inquiries and attempts at resolution. Cmplt. ¶ 81.

Defendants' Unlawful Conduct Threatens Grave And Irreparable Harm To AIS, Its Patients, And The Public

Defendants' unilateral and unlawful directive to force AIS to shut down its dispensing operations is already causing severe and irreparable harms and threatening to cause more catastrophic harms if it remains in place much longer. *Id.* ¶ 82. Defendants' directive has prevented AIS from providing vital and critical medications and services to current patients in Mississippi and across the United States. *Id.* ¶ 83. And if it persists, thousands of current and future chronically ill and vulnerable patients will be unable to receive the benefits of AIS's therapy and care and face serious harm – and possibly death – should their pumps run dry. *Id.* ¶ 84.

Defendants have further undertaken a final agency action without complying with any of the mandatory procedures, including but not limited to the DEA's own hearing and notice requirements. *Id.* ¶ 87. And in doing so, Defendants have further directly contradicted their own directives and past approvals of AIS's dispensing practices and operations – all of which they knew and approved of for years. *Id.* ¶ 88.

Defendants have also deprived AIS of its constitutional right to due process by denying it any opportunity to be heard or challenge their unlawful conduct while depriving it of its protectable property interests. *Id.* ¶ 89. Moreover, by preventing AIS from dispensing its medications from its primary pharmacy, the company cannot remain a going concern. *Id.* ¶ 90. And if AIS cannot

provide patients with their medications and services, AIS's relationships with its patients will be jeopardized, and it will suffer concomitant harm to its goodwill, reputation, and market and competitive position. *Id.* ¶ 91.

STANDARD

This case cries out for a TRO. To obtain one, a party must demonstrate a (1) a substantial likelihood of success on the merits; (2) a substantial threat that failure to grant the injunction will result in irreparable injury; (3) that the threatened injury outweighs any damage that the injunction will cause the adverse party; and (4) that the injunction will not have an adverse effect on the public interest. *See Speaks v. Kruse*, 445 F.3d 396, 399–400 (5th Cir. 2006); Fed. R. Civ. P. 65. A temporary restraining order is "simply a highly accelerated and temporary form of preliminary injunctive relief," *Greer's Ranch Café v. Guzman*, 540 F. Supp. 3d 638, 644–45 (N.D. Tex. 2021) (citation omitted), and is properly issued to "maintain the status quo pending a trial or hearing on the merits." *In re Bahadur*, 441 F. Supp. 3d 467, 473 (W.D. Tex. 2020) (citation omitted). AIS meets the test for such preliminary relief here.

ARGUMENT

I. AIS Is Likely To Succeed On The Merits Of Its Claims.

A. Defendants Have Violated 5 U.S.C. § 706(2)(C) Because The DEA Has No Authority To Issue Its Cease And Desist Directive.

As a threshold matter, the DEA has no authority – statutory or otherwise – to issue directives via cease and desist letters, let alone such letters that could effectively destroy a business and put over 34,000 patients at risk. *See infra* Sections II.B and II.C. Of course, the DEA's directive cites no such authority – because there is none. Ex. B.

According to the DEA, its mission "is to enforce the controlled substances laws and regulations of the United States," which includes "[e]nforcement of the Controlled Substances Act

as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances."[3]

Yet, the CSA does not authorize the DEA to terrorize businesses with cease and desist letters. Consider first the CSA's registration requirements that applicants must satisfy before they can lawfully manufacture or distribute controlled substances. *See* 21 U.S.C. § 823. The Attorney General may suspend or revoke a registrant's authorization *only after* "finding" the registrant has (1) falsified its application; (2) been convicted of a state or federal felony involving controlled substances; (3) had its state license or registration suspended, revoked, or denied; (4) "committed such acts" making its "registration . . . inconsistent with the public interest"; or (5) been excluded from certain programs under Title 42. 21 U.S.C. § 824(a)(1)–(5). The Attorney General may delegate this authority, as well as any other enforcement authority under this subchapter, "to any officer or employee of the Department of Justice," 21 U.S.C. § 871(a), including the DEA.

But in its directive, the DEA not even offer any *allegations* along these lines, let alone make any supportive factual *findings*. Ex. B. Even if it had, the Attorney General must first "serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended." 21 U.S.C. § 824(c)(1). Here, the DEA failed even to explain how AIS failed to comply with § 1306.07(f), thereby falling woefully short of this basic procedural requirement.[4]

Nor is the DEA's letter an execution of its authority under 21 U.S.C. § 878. There, Congress explicitly granted DEA agents authority to engage in limited activities, such as carrying firearms or executing and serving warrants. *See* 21 U.S.C. § 878(a). But Congress

[3] DEA: DEA Mission Statement, *available at* https://www.dea.gov/about/mission (last visited December 15, 2023).

[4] The DEA's directive mechanically block quotes § 1306.07, which includes a citation to 21 U.S.C. § 823(g)(2)(G)(iii), one of the very statutes the DEA claims AIS has violated. Ex. B. But § 823(g)(2)(G)(iii) does not exist.

omitted *any authority* to issue cease and desist letters. *See generally id.* And the Attorney General has not otherwise designated any such authority to the DEA under federal law. Neither Congress nor the Attorney General conferred on the DEA any authority to issue directives via cease and desist letters, and the DEA has long known it. *See United Prescription Servs., Inc. v. Gonzales*, 2006 WL 3804728, at *3 (M.D. Fla. Dec. 22, 2006) (recounting that plaintiff previously obtained an emergency TRO after receiving a DEA cease and desist letter, which DEA later withdrew before the preliminary injunction hearing and explained that it "had received erroneous guidance from its headquarters").

In short, federal law does not authorize the DEA to issue cease and desist letters that can single-handily cripple a registrant's business unless it takes the bold risk of defying the DEA, which is not the case here. *Wedgewood Village Pharm. v. DEA*, 509 F.3d 541, 545 (D.C. Cir. 2007) (vacating DEA's revocation of registration which it revoked after pharmacy continued operating and challenged cease and desist letter). As such, AIS is likely to succeed on the merits of its claim. *See* 5 U.S.C. § 706(2)(C) (giving courts the authority to "hold unlawful and set aside" agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right").

B. Defendants Have Violated 5 U.S.C. § 706(2)(A) Because The DEA's Cease And Desist Directive Is Arbitrary And Capricious.

AIS is also likely to succeed because Defendants' decision to issue the letter was arbitrary and capricious in violation of Section 702(A) of the APA. The APA's arbitrary and capricious standard "requires that agency action be reasonable and reasonably explained." *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1136 (5th Cir. 2021). Courts may consider "only the reasoning articulated by the agency itself" in the administrative record. *Id.* (citation omitted). Here, Defendants' conduct is far from "reasonable" for several reasons.

First, while the DEA stated it had "learned" that AIS had been "providing patient specific pain medications" to treating physician offices, and directed AIS to "cease and desist any further shipments [of its compounded medications] directly to [patients' treating physicians]," Ex. B, the letter provided "no explanation whatsoever" as to how AIS's dispensing practices actually violate the CSA, *Clarke v. Commodity Futures Trading Comm'n*, 74 F.4th 627, 641 (5th Cir. 2023). *See also Bates Drug Stores, Inc. v. Holder*, 2011 WL 1750066, at *3 (E.D. Wash. May 6, 2011) (finding DEA suspension order arbitrary and capricious where it "lack[ed] specific facts demonstrating how those alleged violations were committed").

Second, Defendants have known for years that AIS dispenses specialty compounded medications to vulnerable, high-risk patients whose treating physicians opt to refill their intrathecal pumps in-office – and even confirmed that its practices complied with the CSA. Cmplt. ¶¶ 3, 26, 31; Exs. A & B. Yet it has provided no "reasoned analysis" explaining why AIS is now supposedly operating in violation of the CSA. *Wages & White Lion Invs., L.L.C.*, 16 F.4th at 1139*; see also* Ex. B. The DEA's failure to reasonably explain its departure from its past policy and directive constitutes an "unexplained inconsistency" that is a "hallmark of an arbitrary and capricious change from agency practice." *Data Mktg. P'ship, LP v. United States Dep't of Lab.*, 45 F.4th 846, 857 (5th Cir. 2022) (citing *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016)) (quotations omitted).

Third, Defendants "insufficiently addressed" less drastic remedies before directing AIS to cease almost all of its dispensing activities. *Wages & White Lion Invs., L.L.C.*, 16 F.4th at 1139. The DEA has never challenged, and in fact has routinely approved of, AIS's dispensing practices for years. Ex. A; Cmplt. ¶¶ 59–65. In 2016, the DEA stated it "would consider it permissible under the CSA and DEA regulations for [AIS] to deliver the controlled substance to the practitioner, at his/her registered location" under certain circumstances not limited to the

"maintenance or detoxification treatment" purposes cited in its most recent letter. Exs. A & B. But the DEA failed to consider any potential alternatives to effectively shutting down AIS's operations. Ex. B. This is a "glaring defect[ ]" in light of the "significant" reliance by AIS on the DEA's prior determination. *Clarke*, 74 F.4th at 641.

The directive "gave no reasons for" Defendants' attempt to constructively revoke or suspend AIS's registration, and they cannot salvage their action now using "*post hac* rationalizations." *Clarke*, 74 F.4th at 642. Accordingly, AIS is likely to prevail on its claim. *See Morris & Dickson Co., LLC v. Sessions*, 2018 WL 2393013, at *1 (W.D. La. May 8, 2018).

C. Defendants Have Violated 5 U.S.C. § 706(2)(D) Because The DEA Failed To Comply With Federal Law And Procedures.

Additionally, AIS is likely to succeed on the merits because Defendants plainly failed to comply with federal law and regulations when serving the cease and desist letter on AIS. AIS is a DEA registered pharmacy pursuant to 21 U.S.C. § 823. Cmplt. ¶ 21. Accordingly, registration such as AIS's, granted under the CSA, may be suspended upon a finding that the registrant "failed to comply with any standard referred to in 21 U.S.C. § 823(h)(1)[.]" 21 U.S.C. § 824(a). But before the DEA may take any "action" against a registrant pursuant to 21 U.S.C. § 824(a), it "shall serve upon the . . . registrant an order to show cause why registration should *not* be denied, revoked, or suspended." 21 U.S.C. § 824(c)(1) (emphasis added).[5] The order to show cause "shall contain a statement of the basis for . . . revocation or suspension, including *specific citations to any laws or regulations alleged to be violated* by the . . . registrant." *Id.* § 824(c)(2)(A) (emphasis added). Additionally, the DEA shall provide the registrant the "opportunity to submit a corrective

[5] A registration granted under 21 U.S.C. § 823 may be immediately suspended under § 824(d) upon a finding that there is "is an imminent danger to the public health or safety" evidenced by a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 824(d). The DEA did not and has not evidenced *any* justification for an immediate suspension of AIS's license, let alone a basis to serve a cease and desist letter.

action plan" and the opportunity to be heard at a hearing. 21 U.S.C. §§ 824(c)(1)-(2). At the hearing or proceeding, the government has the burden of proving by a preponderance of evidence that the registrant's continued registration is inconsistent with the public interest. *See* 21 C.F.R. § 1301.44(d).

The DEA failed to comply with its obligations under federal law in multiple ways. *See* Cmplt. ¶¶ 77, 78 & 87; Ex. B. *First*, the DEA does not have *any* authority to serve on registrants a cease and desist letter. *See* 21 U.S.C. § 801 *et seq.*; *id.* § 95l *et seq.*; 21 C.F.R. Part 1300 *et seq.* *Second*, the DEA made no finding that AIS "failed to comply with any standard referred to in 21 U.S.C. § 823(h)(1)[.]" 21 U.S.C. § 824(a). The DEA made no reference at all to any standard, any violation, or any non-compliance by AIS. Ex. B. Nor could it given AIS is in compliance with its earlier conditions and direction.

Third, the DEA did not include with its letter to AIS any "order to show cause." *Id.* The letter did not contain any statement of the basis for any revocation or suspension of AIS's registration. *Id.* Instead, the DEA merely quoted 21 C.F.R. § 1306.07(f) and stated: "[i]n light of these regulations, AIS must cease and desist." *Id.* *Fourth*, and finally, the DEA did not provide AIS the opportunity to submit a corrective action plan or the opportunity to be heard at a hearing at which the DEA would have the burden of proving AIS's continued registration would be inconsistent with the public interest. *Id.*; 21 U.S.C. §§ 824(c)(1)–(2); 21 C.F.R. § 1301.44(d).

The DEA's directive was an brazen attempt to constructively revoke or suspend AIS's registration without adhering to any required process or law. It was flagrantly issued "without observance of procedure required by law" in violation of 5 U.S.C. § 706(2)(D). AIS is therefore likely to prevail on its claim that Defendants' failed to comply with federal law. *See Holder*, 2011 WL 1750066, at *2-3; *Oak Hill Hometown Pharmacy v. Dhillon*, 418 F. Supp. 3d 124, 131 (S.D.W. Va. 2019).

D. Defendants Have Violated AIS's Due Process Rights.

Defendants' cease and desist letter also violated AIS's due process rights under the Fifth Amendment and 5 U.S.C. § 706(2)(B). AIS has a protected interest in its DEA registration to distribute controlled substances. *See Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 828-29 (5th Cir. 1976) (finding Congress designed 21 U.S.C. § 824 to ensure DEA registrant not deprived of property interest without due process in violation of Fifth Amendment). Deprivation of a property interest without either notice and an opportunity for hearing or a finding of "imminent danger" to public health and safety violates due process. *Id.* ("In the absence of that factor there can be no suspension and no seizure without notice and an opportunity to be heard."). But Defendants provided neither. The cease and desist letter thus constitutes a deprivation of AIS's property interests and constitutional right to due process of law, in violation of both the Fifth Amendment and 5 U.S.C. § 706(2)(B). *See Connell v. Shoemaker*, 555 F.2d 483, 487 (5th Cir. 1977).

II. AIS Will Suffer Irreparable Harm Absent Injunctive Relief.

AIS and its patients will be irreparably harmed if immediate injunctive relief is not granted. If forced to comply with the DEA's unlawful directive, AIS will have to effectively halt its HIT business. As a result, AIS would no longer be able to operate, let alone sustain its operations for months to come.

This substantial financial injury alone is irreparable. *Wages & White Lion Invs., LLC*, 16 F.4th at 1142 (stating that " 'substantial financial injury' may be 'sufficient to show irreparable injury' ") (citation omitted). That is the case where, as here, the injury threatens AIS's very existence. *Id.* (finding substantial financial injury that threatened the existence of the company was irreparable); *Texas v. EPA*, 829 F.3d 405, 433 n.41 (5th Cir. 2016) ("Even recoverable costs may constitute irreparable harm where the loss threatens the very existence of the movant's business." (cleaned up)). And even if AIS could somehow survive the substantial financial

turmoil that will follow, it will lose patients and suffer damage to its good will, which is likewise irreparable. *Union Nat. Life Ins. Co. v. Tillman*, 143 F. Supp. 2d 638, 645 (N.D. Miss. 2000) ("A loss of a business' customers and damage to its goodwill are widely recognized as injuries incapable of ascertainment in monetary terms and may thus be irreparable.") (citation omitted).

Moreover, the substantial financial injury to AIS is *not* recoverable. *Texas*, 829 F.3d at 433 n.41 ("Even recoverable costs may constitute irreparable harm where the loss threatens the very existence of the movant's business." (cleaned up)). To be sure, "complying with [an agency order] later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Id.* at 433. That is because "federal agencies generally enjoy sovereign immunity for any monetary damages." *Wages & White Lion Invs., LLC*, 16 F.4th at 1142 (citing cases). Thus, absent a TRO, AIS will suffer harm that "cannot be undone through monetary remedies," which is plainly irreparable. *Deerfield Med. Center v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981).

III. The Threatened Injuries To AIS And Its Patients Far Outweigh Any Potential Injury To Defendants.

The balance of hardships also supports entry of a TRO. Issuing a TRO will harm no one, including the Defendants. As Defendants' directive makes clear, AIS dispenses controlled substances to providers who then fill each patient's unique medication into their intrathecal pump for administration directly into their spine. Ex. B. AIS is not shipping controlled substances to patients, leaving them to their own devices, or diverting these substances to unknown third parties. As such, AIS's continued operation of its HIT business will cause no harm, let alone harm that could outweigh the irreparable harms to AIS and its patients.

Indeed, if AIS cannot ship medications to providers, they will not be able to refill patients' intrathecal pumps, depriving them of vital medication and forcing them to look for

(likely unavailable) alternatives on short notice. These 34,000-plus patients may, in turn, be bedridden from pain, or even die. And this does not even account for the irreparable harm that AIS's business and reputation will suffer if the Defendants can enforce the DEA's unlawful directive. *Supra* Section II.B.

But that is not all. The DEA's own conduct demonstrates that a modest delay will cause it no harm. Since sending the 2016 determination letter, approving AIS's HIT business and dispensing, and conducting countless routine inspections, DEA waited almost *seven years* to send its improper and unlawful letter – and even after substantial time passed from its most recent inspection. Exs. A & B; Cmplt. ¶¶ 55–68. Together, the balance of hardships weigh decidedly in favor of issuing a TRO.

IV. An Injunction Will Serve The Public Interest.

Public interest considerations also weigh strongly in favor of granting immediate injunctive relief in this case, as "the public is served when the law is followed." *Daniels Health Scis., L.L.C. v. Vascular Health Scis., L.L.C.*, 710 F.3d 579, 585 (5th Cir. 2013). In addition, AIS's continued operation of its HIT business – which ships controlled substances directly to providers – poses no imminent threat to public health. Nor would it stem diversion of controlled substances in Texas, Mississippi, or anywhere else. Quite the contrary. Absent a TRO, patients who depend on AIS's life-enhancing and life-saving medications and therapy will not be able to obtain scheduled refills from their providers. This will not only disrupt patients' daily lives, leaving them in constant pain or even bedridden, but cause them severe stress and uncertainly as they (and their doctors) are summarily forced to seek alternatives with essentially no notice.

CONCLUSION

The Court should grant AIS's motion and enter a TRO prohibiting the Defendants from enforcing the unlawful cease and desist letter.

Dated: December 15, 2023

Respectfully submitted,

/s/ Michael Casey Williams

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CERTIFICATE OF SERVICE

I hereby certify that I have electronically filed the foregoing with the Clerk of the Court using CM/ECF system which will send notification of such filing on all counsel of record on December 15, 2023. Counsel for Defendants have also been sent a copy by e-mail.

/s/ Michael Casey Williams
MICHAEL CASEY WILLIAMS